REMARKS

In the outstanding Office Action, claims 1 to 15 were presented for examination. Applicant notes with appreciation the indication of allowable subject matter in claims 5, 7, 8, 13 and 15. Claims 2 was rejected on formal grounds under 35 U.S.C. §112. In addition, rejection was advanced variously on the basis of 35 U.S.C. §102 or §103 against claims 1-4, 6, 9-12 and 14 as being anticipated by or unpatentable in view of references to HAEMACCEL® and Ecanow et al.

The Office Action has been most carefully studied. In this amendment has added new claims further defining the subject matter to be protected. In addition, claims 1-15 have been amended. The new and amended claims have been carefully written to avoid any questions under 35 U.S.C. §112, in accordance with the guidelines and requirements set forth in the outstanding Office Action. Accordingly, as will be discussed in detail below, it is believed that the application is clearly in condition for allowance.

Specification

The specification will be amended to overcome the various clerical deficiencies kindly pointed out by the Examiner when the application is otherwise in condition for allowance.

Allowable Claims

The indications of allowability of claims 5, 7, 8, 13 and 15 are greatly appreciated and applicant is willing to rewrite the claims as proposed by the Office, if necessary. However, because other claims, including the respective base claims are believed

allowable, as explained herein, applicant will respectfully defer such rewriting amendment pending reconsideration of the rejection of such other claims.

Claim Amendments

Claims 1, 2, 9 and 10 have each been amended without narrowing or to make explicit language that was previously inherent. Other claims have been amended in minor clerical respects, without narrowing.

Claim Rejections - 35 U.S.C. §112 Indefiniteness

Claim 2 has been amended to overcome the rejection, also without narrowing. Amended Claim 2 clearly requires that the monomer have a molecular weight of 10,000 to 50,000 Daltons. Pursuant to the language of claim 2, the isoelectric point is not changed by multimerization and is less than 8 for the monomer, dimer, trimer or tetramer.

Claim Rejections - 35 U.S.C. §102(b) Anticipation

Turning now to the rejection of claims 1-4, 6, 9-12 and 14 as anticipated by HAEMACCEL® et al., claims 1-4, 6, 9-12 and 14 are believed clearly distinguished from this reference or any other art known to applicant.

Independent base claims 1, 2, 9 and 10 in their original form were directed to recombinant gelatin-like polymers and are therefore clearly distinguished from HAEMACCEL®'s gelatin which is not recombinant and is derived from bovine material (See the data sheet filed herewith.) Nevertheless, claims 1, 2, 9 and 10 have been amended to recite that the recombinant gelatin-like polymer is not crosslinked by chemical modification, as can be understood from applicant's specification particularly

in light of the discussion at page 1, lines 21-24. This amendment merely makes explicit matter inherent in the claims before amendment and serves to remove any question in the mind of the reader with a view to facilitating prompt prosecution and early allowance of the application. Clearly, therefore, HAEMACCEL® does not anticipate the amended claims.

In considering claims 2 and 10, it will be understood that the "multimers" of the invention are quite different from cross-linked materials. Multimers are simply repeats of a specific amino acid sequence.

As may further be seen from the data sheet and the package insert cited by the Office, the material disclosed in the HAEMACCEL® package insert is not only not a recombinant gelatin-like protein, but rather is a gelatin composition obtained by degrading bovine-extracted gelatin, followed by chemical modification, specifically, cross-linking via urea-bridges. Thus the HAEMACCEL® product appears to be one of the prior art gelatin compositions described on page 1, lines 21-29, of applicant's specification. Such product is believed to lack the advantages obtainable with preferred embodiments of the recombinant gelatin compositions according to the claimed invention. Such advantages include:

- a high blood clearance rate (see top of page 2 of Package Insert);
- a risk of BSE contamination (due to the bovine source);
- susceptibility to proteolytic degradation (see top of page 2 of Package Insert);
- risk of hypersensitivity reactions; and
- the degraded fragments are a heterogenous mixture with a mean molecular weight around 30,000 D, while compositions according to the claimed invention are more homogenous.

Claim Rejections - 35 U.S.C. §103 Unpatentability

With regard to the obviousness rejection of the claims over Escanow in view of HAEMACCEL®, Escanow does not disclose a plasma expander, but a "whole blood substitute". Synthetic "whole blood" is fundamentally different from blood substitutes, such as plasma expanders (see Column 1, line 36-39, of Escanow). Both the purpose (whole blood substitution rather than volume expansion by addition) as well as the components are fundamentally different. Especially, the whole blood substitute of Escanow comprises two gelatins with different isoelectric point, one between 2-6 and the other between 8-10 (see claim 1 and 2 of Escanow). This combination is purported to solve the problem of obtaining a coacervate phase in the preparation of whole blood.

In contrast, the claimed invention provides compositions wherein the isoelectric point of the proteins is below 8. One of the problems solved by the present compositions is the high blood clearance rate of gelatin-comprising plasma expanders. Pursuant to the invention, it was found that the blood clearance rate could be controlled by controlling molecular weight and net negative charge, as determined by the isoelectric point, of the gelatin-like proteins. In particular, the isoelectric point desirably is below about 8.

The problem of blood clearance of gelatin-like proteins is not addressed by either Escanow nor HAEMACCEL®, nor are any solutions to this problem proposed. A skilled person would not arrive at the present compositions by adding a "saline solution" to the compositions of Escanow, as suggested by the Examiner. Such compositions would be completely unsuitable as plasma expanders and would not solve the problem of high blood clearance rates, as such compositions would contain gelatin of an isoelectric point above 8.

Furthermore, HAEMACCEL® provides no guidance as to how a plasma expander with lower blood clearance could be obtained. A skilled person desiring to

solve this problem would not look for a solution in Escanow, as Escanow only refers to whole blood compositions. Even if a skilled person would combine HAEMACCEL® with Escanow, he or she would at most arrive at a composition having 2 gelatins with different isoelectric points, one above 8 and one below 8, which however would not solve the problem. Clearly, applicant's claimed use of recombinant gelatins of particular molecular weight and with an isoelectric point of less than 8 is not obvious to a skilled person and the claims now of record are clearly and patentably distinguished from this combination of references or any other references or combination of references known to applicant.

In view of the above amendments and the discussion relating thereto, it is respectfully submitted that the instant application, as amended, is in condition for allowance. Such action is most earnestly solicited. If for any reason the Examiner feels that consultation with Applicant's representative would be helpful in the advancement of the prosecution, they are invited to call the telephone number below for an interview.

Respectfully submitted,

By: _____

Anthony H. Handal
Reg. No. 26,275 Ph: (212) 536-4870
Roger Pitt
Reg. No. 46,996 Ph: (212) 536-4867

KIRKPATRICK & LOCKHART LLP
599 Lexington Avenue (32nd Floor)
New York, NY 10022-6030

Certificate of Mailing
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope, postage prepaid, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 2, 2004.

_____

Anthony H. Handal
Reg. No. 26,275
Roger Pitt
Reg. No. 46,996